Remarks

EPA 1 159 956 A describes formulations which require the use of a penetration enhancer. See abstract, page 3, line 12. There is a description of a formulation that contains in addition to carrier and penetration enhancer 0-2% ketoconazole and 0-0.05% desonide (see tables 1-4, 7-10). As previously discussed, the carrier can alter the potency of the applied steroidal anti-inflammatory and antifungal. Not only is this an issue when one includes a penetration enhancer, but it causes the steroidal anti-inflammatory to penetrate into the dermis, leading to higher potency of the anti-inflammatory and risking the side effects applicants avoids. This also causes the anti-fungal portion of the composition to be less efficacious at the epidermis, which is the site of the fungal infection.

Referring to applicants' specification, paragraph 3 of application teaches away from a formulation where the anti-inflammatory penetrates into the dermis: "Steroids can penetrate the skin and cause undesirable side effects, including skin atrophy, hypopigmentation, suppression of the hypothalamic-pituitary-adrenal axis, Cushing's syndrome, and appearance of telangectasias." Paragraph 8 states "The composition can be formulated in any dosage form suitable for topical administration." The result is that one would select a carrier that is topical (i.e., applied to the epidermis) and which does not cause the steroids to penetrate the skin and cause undesirable side effects. This express limitation has now been incorporated into the claims.

Favorable action on the claims is earnestly solicited.

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